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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/241,455

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NIKOLAI M. KRIVITSKI

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01/09/2004

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 01/09/2004

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/241,455

Applicant(s)

KRIVITSKI, NIKOLAI M.

Examiner

Brian Szmaj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6,9-19,22 and 24-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-19,25-29 and 39-42 is/are allowed.
- 6) ☒ Claim(s) 2-6,9-15,22,24 and 30-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4-6 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 4-6 and 13 recite the limitation "the blood property change port" in lines 1-2 of each of the claims. There is insufficient antecedent basis for this limitation in the claims.

4. Claims 12 and 14 recite the limitation "the port" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 also recites elements that were added to Claim 9 in the latest amendment.

Claim Rejections - 35 USC § 102 & 35 USC § 103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Quinn et al ('654).

Quinn et al, discloses a multi-lumen, multi-parameter catheter and further disclose a catheter; a temperature gradient generator on the catheter located to alter a blood parameter external to the catheter; means for effecting a corrective procedure; a blood parameter sensor connected to the catheter and spaced at a fixed distance from the temperature gradient generator to sense the altered blood parameter external to the catheter and provide a signal determining a blood flow; and a controller connectable to the temperature gradient generator and the blood parameter sensor to calculate the blood flow. See Column 3, lines 25-35 and 48-63; Column 4, lines 25-31 and 60-67; Column 5, lines 1-7 and 26-49; and Column 6, lines 35-44.

8. Claims 15, 32, 33, 35, 37 and 38 rejected under 35 U.S.C. 102(b) as being anticipated by Degironimo et al.

Degironimo et al disclose an injection system and further disclose a dilution indicator source; a catheter connectable to the dilution indicator source, the catheter having means for performing a vascular corrective procedure, a dilution indicator port for passing a dilution indicator therethrough to pass from the catheter and a downstream

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sensor a fixed distance from the indicator port for producing a signal corresponding to passage of the dilution indicator external to the catheter; a controller connected to the dilution indicator source and the sensor for calculating a blood flow in response to the signal from the sensor; the sensor detects one of electrical impedance and electrical resistance; the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood; the indicator source connected to the catheter for providing a known rate and volume of dilution indicator source to the indicator introduction port; and the volume of indicator source is one of a bolus and a constant infusion. See Column 3, lines 26-68; Column 4, lines 1-10; Column 6, lines 7-25.

Even though Degironimo et al discloses the use of the balloon for stabilizing the catheter in the heart and not for a corrective vascular procedure, the current claim language constitutes an intended use of the balloon, since it states: "means for performing a vascular corrective procedure".

9. Claims 2, 3, 9-14, 30, 31, 34 and 36 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Quinn et al ('654).

Quinn et al, as discussed above, disclose a thermodilution catheter and further disclose a catheter body having a stenosis reducing member selectively actuateable to reduce a stenosis in a vessel; one of a local heat source and a local heat sink affixed to the catheter body for inducing a blood property change to blood flowing external to the stenosis reducing catheter, the one of local heat source and local heat sink located at a fixed distance from the stenosis reducing member; a sensor affixed to the catheter body

and spaced at a given distance from the local heat source and local heat sink for providing a signal corresponding to a change in a blood property external to the stenosis reducing catheter; a controller operably connected to the sensor to calculate the flow rate corresponding to the signal from the downstream sensor; a port that includes an aperture for introducing a blood property variant; the port and sensor are spaced apart; the sensor detects changes in one of electrical impedance and electrical resistance; the sensor detects one of an optical, electrical, chemical or physical property of the blood; a local temperature gradient generator; one of the sensor and the catheter is configured to locate the sensor with respect to the vessel to minimize wall effects; and the volume of indicator is one of a bolus and a constant infusion. See Column 3, lines 25-35 and 48-63; Column 4, lines 25-31 and 60-67; Column 5, lines 1-7 and 26-49; and Column 6, lines 35-44.

Even though Quinn et al discloses the use of a balloon for stabilizing the catheter in the heart and not for a corrective vascular procedure, it would have been obvious to one of ordinary skill in the art to utilize the same balloon for a corrective procedure since the design of the balloon essentially remains the same.

Allowable Subject Matter

10. The following is a statement of reasons for the indication of allowable subject matter: Claims 16-19, 25-29 and 39-42 are allowable since no prior art could be found teaching or suggesting a method for monitoring blood flow during a vascular corrective procedure comprising: reducing the stenosis; and determining at a controller connected

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to the indicator source and the sensor a change in blood flow past the downstream sensor.

Response to Arguments


11. Applicant's arguments, see Paper No. 27, filed November 7, 2003, with respect to the rejection(s) of claim(s) 2, 3, 9-14, 22, 24, 30, 31, 34 and 36 under Alt ('234) and Quinn et al ('654) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Quinn et al ('654).

12. Applicant's arguments, see Paper No. 27, filed November 7, 2003, with respect to claims 16-19, 25-29 and 39-42 have been fully considered and are persuasive. The rejection of Alt ('234) has been withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (703) 308-3737. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-2701. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

BS 


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